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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,221	12/13/2001	Nathan S. Lewis	CIT1300-1	9894

20985 7590 12/01/2004

FISH & RICHARDSON, PC
12390 EL CAMINO REAL
SAN DIEGO, CA 92130-2081

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,221

Applicant(s)

LEWIS ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/30/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of August 30, 2004 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed August 30, 2004 ("Amendment") have been fully considered but they are not persuasive.

Rejection of claims 1, 2, and 9-15 under 35 U.S.C. § 112, first paragraph, as not being enabled for the full scope of the claims

Applicants assert that they have "(1) demonstrated alcohol as a species as well as further identified in Appendix A; (2) these species have a reasonable correlation to other molecular analytes; and (3) the system and methods of the invention are based upon predictable factors including electrical and mechanical measurement to obtain signal profiles." See the bottom of page 9 bridging to top of page 10 of the Amendment. The examiner respectfully disagrees. As for alcohols having a "reasonable correlation" to other analytes, alcohols, such as benzyl alcohol and 1,4-butanediol (Figure 5A of Applicants' disclosure), have very little physical or chemical

“correlation” to hormones, nucleic acids, polypeptides, antibodies, enzymes, or carbohydrates. Some lipids and fatty acids may have some structural similarities to alcohols but would not be expected to have the same chemical properties because of different functionalities. An alcohol group is different from a carboxylic acid group. Applicants are requested to explain the physical or chemical correlation between benzyl alcohol (or another alcohol from Figure 5A) and a hormone, nucleic acid, polypeptide, antibody, enzyme or carbohydrate. As for Applicants’ system and methods of invention being based upon predictable factors, Applicants’ claims include obtaining a signal profile indicative of enzymatic activity, a binding activity, and a modulating activity using an array of differentially responsive optical, electrical, magnetic, mechanical, physical sensors or a combination thereof. Applicant is requested to explain how predicting the inhibitory activity of gaseous alcohols on cytochrome P-450 aniline p-hydroxylation using an array of electrical resistances establishes the predictability of enzymatic activity using an array of optical and magnetic sensors, let alone enables such a prediction.

Applicants have provided an article (Sisk and Lewis) in Appendix A of their Amendment to bolster their position on the enablement issue. This article does not help their position much. The analytes are alcohols, halogenated hydrocarbons, aromatics, unsubstituted hydrocarbons, and esters, which are not much closer to hormones, nucleic acids, polypeptides, antibodies, enzymes, or carbohydrates than the alcohols of their disclosure. The chemical properties which could be discerned with the sensor array were chemical functionalities, that is, whether the analyte is an alcohol, halide, aromatic, hydrocarbon, or ester. The physical properties which could be discerned by the sensor array were molecular weight and dipole moment. These properties bear little kinship to enzymatic activity, binding activity, or modulating activity.

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Furthermore, the sensor array was an array of electrical resistances. It is not readily apparent that even the same properties for the same analytes in the article could be discerned using a sensor array having a combination of optical and magnetic sensors.

For the reasons set forth above and in the previous Office action claims 1, 2, and 9-15 exceed the scope of enablement.

Rejection of claims 3-8 under 35 U.S.C. § 112, first paragraph, as not being enabled

Applicants essentially rely on their comments regarding the rejection of claims 1, 2, and 9-15 under 35 U.S.C. § 112, first paragraph, which have been addressed above. Discerning the inhibitory effect of gaseous alcohols on cytochrome P-450 aniline p-hydroxylation using an array of electrical resistances does not enable discerning enzymatic activity or binding activity of antibodies using an array of optical and magnetic sensors.

Status of the Rejections Pending since the Office Action of May 11, 2004

3. All double patenting rejections are withdrawn.

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4. The rejection of claims 1, 2, and 9-15 under 35 U.S.C. § 112, first paragraph, are maintained. Applicants' amendment to claim 1 does not obviate the enablement concerns raised in the previous office action and discussed above.

5. The rejection of claims 3-8 under 35 U.S.C. § 112, first paragraph, are maintained. Applicants' amendment to claim 1 does not obviate the enablement concerns raised in the previous office action and discussed above.

6.

7. The rejections of claims 1, 2, and 11 under 35 U.S.C. §102(b) as being anticipated by Buchelli are withdrawn.

8. The rejections of claims 1-4, 11, and 12 under 35 U.S.C. §102(a) as being anticipated by Shiers are withdrawn.

9. The rejections of claims 1-4, 11, 12, 14, and 15 under 35 U.S.C. §102(a) as being anticipated by Bodenhfer are withdrawn.

10. The rejections of claims 9 and 10 under 35 U.S.C. §103(a) as being obvious over Bodenhfer are withdrawn.

Final Rejection

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner

AU 1753

November 30, 2004